

REMARKS

Claims 1-47 are pending in the application.

Claims 6-21, 24 and 26-47 have been withdrawn from consideration as directed to a non-elected invention. Claims 6-21, 24 and 26-47 have now been cancelled. Applicants reserve the right to pursue the subject matter of the cancelled claims in a divisional or continuation application.

Claims 1-5, 22-23 and 25 have been examined. Applicants thank the Examiner for the indication that Claims 1 and 2 are allowed. Claims 5, 22 and 25 have been amended. None of these amendments introduces new matter.

Favorable reconsideration and allowance of all pending claims are respectfully requested.

I. Claim Objections

Claim 22 was objected to for depending from a non-elected claim, and Claim 25 was objected to for reciting non-elected sequences. In response, Claims 22 and 25 have been amended to delete all non-elected subject matter. Thus, withdrawal of this objection is respectfully requested. As the Examiner presented no other objections or rejections to Claims 22 and 25, indication that Claims 22 and 25, as amended, are allowed is respectfully requested.

II. Double Patenting Objection

Claim 5 was objected to as allegedly being a substantial duplicate of Claim 2. The Examiner asserts that the scope of Claim 5 does not differ from that of Claim 2 “as both claimed DNA sequences must comprise SEQ ID NO:1”. This objection is respectfully traversed.

Claim 2 depends from Claim 1, and Claim 5 depends from Claim 4. The scope of a dependent claim is determined based upon reading it in context with the claim from which it

depends. However, the Examiner has not asserted that Claim 4 is a substantial duplicate of allowed Claim 1. Claim 1 is directed to “an isolated polynucleotide comprising a nucleotide sequence encoding an MLK4 gene product from a human,” and Claim 4 is directed to “an isolated polynucleotide molecule *consisting of a nucleotide sequence that is a substantial portion of a polynucleotide molecule* comprising a nucleotide sequence encoding an MLK4 gene product from a human” (emphasis added). Claim 5 has been currently amended to incorporate additional language from Claim 4 to emphasize that the isolated polynucleotide claimed in Claim 5 comprises the substantial portion of a polynucleotide molecule comprising a nucleotide sequence encoding an MLK4 gene product from a human. Applicants submit that Claim 2 is directed to a polynucleotide sequence that encodes an MLK4 gene product, whereas Claim 5 is directed to a polynucleotide sequence that encodes a substantial portion of an MLK4 gene product. Thus Claim 5 can encompass less than the entire nucleotide sequence of SEQ ID NO:1.

Therefore, Applicant's respectfully submit that Claims 2 and 4 are not substantially duplicative. Reconsideration and withdrawal of this objection is respectfully requested.

III. The Written Description Rejections

A. Claims 3-4 have been rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to be enabled by the specification.

With respect to Claim 3, the Examiner asserts that the specification is enabling for isolated DNA molecules that are at least 90% homologous to SEQ ID NO:1 while being capable of encoding products with MLK4 activity, but does not provide enablement for any homologous sequence to SEQ ID NO:1. This rejection is respectfully traversed.

As noted by the Examiner, the specification defines the term “homologous” on page 8, line 27 through page 9, line 3. However, contrary to the Examiner's statement that the defined

term “homologous” includes the percent identity but no function, the term homologous actually includes parameters of function, hybridization capability and function.

Briefly restated, a DNA sequence is considered to be “homologous” to SEQ ID NO:1 if it has a nucleotide sequence that: (i) includes one or more silent changes to the nucleotide sequence according to the degeneracy of the genetic code or is at least 70%, more preferably at least about 80%, and most preferably at least about 90% identical to SEQ ID NO:1; (ii) hybridizes to the complement of a polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:2 under moderately stringent conditions, which conditions are specifically detailed on page 8, line 36 through page 9, line 3; and (iii) is useful in practicing the invention. The phrase “useful in practicing the invention” with respect to an MLK4-related polynucleotide molecule is clearly defined on page 9, lines 13-25, to require that the polynucleotide molecule: (i) encodes a peptide that can be used to generate antibodies that immunospecifically recognize the MLK4 product from a eukaryotic cell; or (ii) can detect the presence of the MLK4 transcript in a test sample; or (iii) can enable a method for altering the regulation or expression of the endogenous MLK4 gene (such as by gene activation or inactivation techniques, e.g. insertion of a transcriptional activator sequence into an intron, or deletion of one or more exons); or (iv) can be used to amplify a polynucleotide molecule comprising the nucleotide sequence of the MLK4 ORF in a eukaryotic cell using standard amplification techniques such as PCR.

Accordingly, Applicants respectfully submit that the term “homologous” is clearly defined in the specification to describe, in terms of the both structure and function, polynucleotides which fall within the scope of Claim 3. Applicants further submit that only routine experimentation would be required for an individual having ordinary skill in the art to

determine whether or not a polynucleotide was “homologous” to SEQ ID NO:1 in accordance with the teachings of the specification.

Thus, reconsideration and withdrawal of this rejection of Claim 3 is respectfully requested.

With respect to Claim 4, the Examiner opines that the term “substantial portion” is defined in the specification “as a DNA fragment (of at least 45 bases in length) capable of encoding any 15 amino acid fragments of SEQ ID NO:2 with no specific function.”

Contrary to this assertion of the Examiner, the term “substantial portion” is defined on page 10, lines 21-27, to mean “a polynucleotide molecule consisting of less than the full length of the nucleotide sequence of SEQ ID NO:1 or homologous polynucleotide thereof, but comprising at least 20%, and more preferably at least about 30%, of the length of said nucleotide sequence, and that is useful in practicing the invention, as usefulness is defined above for MLK4-related polynucleotide molecules.” The phrase “useful in practicing the invention” for MLK4-related polynucleotide molecules is clearly defined on page 9, lines 13-25, to require that the polynucleotide molecule: (i) encodes a peptide that can be used to generate antibodies that immunospecifically recognize the MLK4 product from a eukaryotic cell; or (ii) can detect the presence of the MLK4 transcript in a test sample; or (iii) can enable a method for altering the regulation or expression of the endogenous MLK4 gene (such as by gene activation or inactivation techniques, e.g. insertion of a transcriptional activator sequence into an intron, or deletion of one or more exons); or (iv) can be used to amplify a polynucleotide molecule comprising the nucleotide sequence of the MLK4 ORF in a eukaryotic cell using standard amplification techniques such as PCR.

Accordingly, Applicants respectfully submit that the term “substantial portion” is clearly defined in the specification to describe, in terms of the both structure and function, polynucleotides which fall within the scope of Claim 4. Applicants further submit that only routine experimentation would be required for an individual having ordinary skill in the art to determine whether or not a polynucleotide is a “substantial portion” of a polynucleotide comprising a nucleotide sequence encoding an MLK4 gene product based upon the identity of such sequence to SEQ ID NO:1, and the function of such sequence to be useful in practicing the invention as required under the definition of “substantial portion.”

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection of Claim 4.

Applicants also note that the Examiner has mistakenly interpreted a non-limiting embodiment of the term “substantial portion,” provided on page 10, lines 27-29, as a limitation of Claim 4. In this non-limiting embodiment, a substantial portion of the MLK4-related polynucleotide molecule consists of a nucleotide sequence that encodes a peptide fragment of a human MLK4 gene product of the present invention. As defined on page 10, lines 29-33, a “peptide fragment” of an MLK4-related polypeptide refers to a polypeptide consisting of a subsequence of SEQ ID NO:2, which is useful in practicing the invention (as usefulness is defined for MLK4-related polypeptides) and a peptide fragment is preferably at least about 15 amino acid residues, and more preferably at least about 30 amino acid residues in length. The phrase “useful in practicing the invention” for MLK4-related polypeptide is clearly defined on page 10, lines 15-18 and recites “where the polypeptide can be used to raise antibodies against an MLK4 gene product from a eukaryotic, preferably mammalian, and most preferably human cell or

tissue, or to screen for compounds that modulate MLK4 activity or production in such a cell or tissue.”

Thus, Applicants respectfully submit that as the specific embodiment discussed in this paragraph is a non-limiting embodiment, the limitations of the defined term for peptide fragment cannot be read into Claim 4 which is directed to a substantial portion of a polynucleotide molecule, which is independently defined to have a structure of at least 20% of the full length of the nucleotide sequence of SEQ ID NO:1 and to be useful in practicing the invention, as defined in the specification.

B. Claims 3-4 have been rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to satisfy the written description requirement. The Examiner opines that the subject matter of Claims 3 and 4 is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

This rejection is respectfully traversed for the following reasons. First, Applicants fully supported Claims 3-4 in the specification at least at page 2, lines 15-25, and pages 8-10. Secondly, the terms “homologous” and “substantial portion” are clearly defined in the specification to require that the polynucleotide molecule have a defined structure and defined function.

With respect to Claim 3, the term “homologous” is clearly defined on page 8, line 27 through page 9, line 3, to require that a DNA sequence is considered to be “homologous” to SEQ ID NO:1 if it has a nucleotide sequence that: (i) includes one or more silent changes to the nucleotide sequence according to the degeneracy of the genetic code or is at least 70%, more preferably at least about 80%, and most preferably at least about 90% identical to SEQ ID NO:1;

(ii) hybridizes to the complement of a polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:2 under moderately stringent conditions, which conditions are specifically detailed on page 8, line 36 through page 9, line 3; and (iii) is useful in practicing the invention. The phrase “useful in practicing the invention” with respect to an MLK4-related polynucleotide molecule is clearly defined on page 9, lines 13-25, to require that the polynucleotide molecule: (i) encodes a peptide that can be used to generate antibodies that immunospecifically recognize the MLK4 product from a eukaryotic cell; or (ii) can detect the presence of the MLK4 transcript in a test sample; or (iii) can enable a method for altering the regulation or expression of the endogenous MLK4 gene (such as by gene activation or inactivation techniques, e.g. insertion of a transcriptional activator sequence into an intron, or deletion of one or more exons); or (iv) can be used to amplify a polynucleotide molecule comprising the nucleotide sequence of the MLK4 ORF in a eukaryotic cell using standard amplification techniques such as PCR.

Accordingly, Applicants respectfully submit that the term “homologous” is clearly defined in the specification to describe, in terms of the both structure and function, polynucleotides which fall within the scope of Claim 3. Applicants further submit that the subject matter of Claim 3 is described in the specification in such a way as to convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed.

With respect to Claim 4, the term “substantial portion” is clearly defined on page 10, lines 21-27, to mean “a polynucleotide molecule consisting of less than the full length of the nucleotide sequence of SEQ ID NO:1 or homologous polynucleotide thereof, but comprising at least 20%, and more preferably at least about 30%, of the length of said nucleotide sequence, and

that is useful in practicing the invention, as usefulness is defined above for MLK4-related polynucleotide molecules.” The phrase “useful in practicing the invention” with respect to an MLK4-related polynucleotide molecule is clearly defined on page 9, lines 13-25, to require that the polynucleotide molecule: (i) encodes a peptide that can be used to generate antibodies that immunospecifically recognize the MLK4 product from a eukaryotic cell; or (ii) can detect the presence of the MLK4 transcript in a test sample; or (iii) can enable a method for altering the regulation or expression of the endogenous MLK4 gene (such as by gene activation or inactivation techniques, e.g. insertion of a transcriptional activator sequence into an intron, or deletion of one or more exons); or (iv) can be used to amplify a polynucleotide molecule comprising the nucleotide sequence of the MLK4 ORF in a eukaryotic cell using standard amplification techniques such as PCR.

Accordingly, Applicants respectfully submit that the term “substantial portion” is clearly defined in the specification to describe, in terms of the both structure and function, polynucleotides which fall within the scope of Claim 4. Applicants further submit that the subject matter of Claim 4 is described in the specification in such a way as to convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed.

Reconsideration and withdrawal of this rejection of Claims 3-4 is respectfully requested.

IV. Anticipation Rejection

Claim 3 was rejected under 35 U.S.C. § 102(b) as being anticipated by Bennett et al. Bennett et al. was stated to teach a DNA sequence that has 43.9% identity to SEQ ID NO:1 and thus could be considered to be “homologous” to SEQ ID NO:1. This rejection is respectfully traversed.

The term “homologous” is clearly defined in the specification at page 8, line 27 through page 9, line 3, to require that a DNA sequence is considered to be “homologous” to SEQ ID NO:1 if it has a nucleotide sequence that: (i) includes one or more silent changes to the nucleotide sequence according to the degeneracy of the genetic code or is at least 70%, more preferably at least about 80%, and most preferably at least about 90% identical to SEQ ID NO:1; (ii) hybridizes to the complement of a polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:2 under moderately stringent conditions, which conditions are specifically detailed on page 8, line 36 through page 9, line 3; and (iii) is useful in practicing the invention.

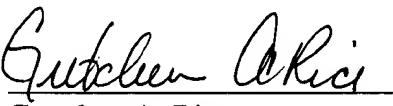
As the DNA sequence disclosed by Bennett et al. is less than 70% homologous to SEQ ID NO:1, such sequence is outside the scope of Claim 3. Reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit the present claims are in condition for allowance, which action is earnestly solicited. The Examiner is invited to contact the undersigned by telephone should any issues remain outstanding.

Respectfully submitted,

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